PSY6

CONTRIBUTIONS OF THE HUNTER OUTCOME SURVEY (HOS) TO ADVANCING UNDERSTANDING OF HUNTER SYNDROME

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OBJECTIVES: To review how the Hunter Outcome Survey (HOS), a physician-driven, multinational, observational survey supported by Shire HGT, has helped advance the understanding and management of Hunter syndrome—a rare, X-linked disorder of glycosaminoglycan (GAG) metabolism caused by deficiency of the enzyme iduronate-2-sulfatase. **METHODS:** HOS was established in 2005 to help understand the natural history of Hunter syndrome and the long-term safety and effectiveness of enzyme replacement therapy (ERT) with idursulfase. Data such as demographics, signs/symptoms, investigations, developmental milestones and laboratory test data are collected for patients with a confirmed diagnosis. Three working groups (Natural History, Cardiac and CNS) have been established to further data collection/interpretation in the respective fields. **RESULTS:** As of January 2009, 98 clinics across 23 countries have enrolled 642 patients. The first peer-reviewed paper, published in 2008, reported that the median ages of onset of symptoms and diagnosis were 1.5 and 3.5 years, respectively; the average height of Hunter children was normal up to approximately 9 years of age, following which it fell below the third percentile (Wraith et al., 2008). Other important findings include: by 6 years of age half of patients showed cardiovascular abnormalities (Wraith et al., 2007); the majority of patients developed airway involvement in childhood (Burton et al., 2008); and prior to diagnosis, the most common clinical symptoms were characteristic facial features, enlarged liver and spleen, hernia and otitis (Beck et al., 2007). **CONCLUSIONS:** In the short time HOS has been running, it has provided important real-world data on Hunter syndrome. Data analyses have identified the need for early diagnosis, to enable institution of appropriate therapeutic management. Through ongoing collaboration between participating physicians and working groups, HOS will continue to expand the evidence base of knowledge around Hunter Syndrome and be a valuable tool to evaluate the effectiveness of ERT and help optimize patient care.

PSY7

DISEASE FLARES AMONG PATIENTS WITH CROHN'S DISEASE

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OBJECTIVES: Crohn's disease (CD) causes inflammation in the lining of the small or large intestine and is characterized by disease flares. This study quantified the incidence of disease flares among adult patients with CD, and assessed the impact of flares on resource utilization. **METHODS:** Cross-sectional data were collected via the Inflammatory Bowel Disease (IBD) Study Project during Q3 2008. Study participants were recruited from an Internet panel and were reported to have IBD as diagnosed by a physician. All survey respondents were aged ≥18 years. **RESULTS:** A total of 500 patients with CD completed the survey. Overall, 32.0% of all CD patients reported one or more flares per week, while an additional 26.8% reported one or more flares per month. Patients reporting one or more flares per week were significantly younger (42.2 years) and had CD for shorter lengths of time (11.7 years) than patients with less frequent disease flares. The former were more likely to classify their disease as moderate to severe, uncontrolled, and more bothersome. The majority of disease flares lasted less than one week and were of moderate severity. Patients experiencing more frequent disease flares were significantly more likely to have been hospitalized (28.8% vs. 6.5%), have longer lengths of stay (2.2 days vs. 0.9 days), visited the emergency room (40.6% vs. 6.5%), and visited their gastroenterologist (60.6% vs. 32.3%) in the past six months as a result of their CD. These patients were also more likely to have higher degrees of work productivity loss. **CONCLUSIONS:** The majority of patients with CD experience disease flares at least monthly, and the more frequent the flares, the greater the resource utilization and disruption to work life. Treatments that adequately control disease flares may result in cost offsets and should be examined.

PSY8

IMPORTANCE OF ROUTINE URINE DRUG TESTING IN THE CHRONIC PAIN PATIENT POPULATION

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OBJECTIVES: To describe rates of inappropriate utilization, abuse, and diversion in a population of patients who were prescribed chronic opioids, as measured by urine drug testing (UDT) in the clinical setting. A secondary objective is to inform providers, payors and policy-makers about the importance of routine monitoring of patients on chronic opioids. **METHODS:** A retrospective analysis was conducted of a database containing results from all urine drug tests conducted between January 2006 and September 2008, by Ameritox, Ltd. using their RxGuardian(sm) monitoring algorithms, for patients whose physicians ordered the test in order to screen for non-compliance. **RESULTS:** Data from over 800,000 patient test samples obtained from over 500,000 unique patients showed that 75% of patients were deemed "noncompliant" with their prescribed pain regimen. Of patients determined to be noncompliant; 39% were found to not have the prescribed opioid present, 29% had non-prescribed opioid medications present, 27% had a drug level higher than expected, 15% had a drug level lower than expected, and 11% had illicit drugs detected in their urine. **CONCLUSIONS:** The high observed rate of noncompliance in this patient population implies high rates of non-adherence, overuse, and diversion of prescribed opioid medications. Previous research has compared direct per-patient costs of insured opioid abusers versus non-abusers, and found significantly higher health care costs for opioid abusers. These higher costs have been attributed to increased utilization of services and prescription products, as well as more frequent comorbidities. Utilizing a UDT that can not only detect the presence of other non-prescribed and illicit drugs, but also is sensitive enough to determine whether the patient is adherent to their current regimen provides a powerful tool for clinicians seeking to identify and decrease non-compliance, overuse, and diversion of controlled substances in their practice.

PSY9

USING UTILIZATION RECORDS TO ESTIMATE THE BURDEN OF OBESITY IN ADULTS LIVING IN ONTARIO

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OBJECTIVES: To present an overview of the burden of obesity in adults by using the richness of a Canadian population health survey linked to Ontario administrative databases. **METHODS:** The records of all Ontarians who participated in the Canadian Community Health Survey (CCHS), cycle 1.1 (2000/2001) and provided consent to data linkage with administrative databases were linked to the Ontario Health Insurance Program (OHIP) claims database and the Discharge Abstract Database (DAD) In-Patient and Day Procedure database. Prevalence of obesity in this adult population was documented using the body mass index (BMI) calculated by Statistics Canada for adults aged 20–64 years of age. Socio-demographics (e.g. age, gender, education), medical characteristics (e.g. comorbidities), health related quality of life (Health Utility Index 3), self-reported health and one-year physician and hospitalization costs were described per BMI category (i.e. underweight, normal weight, overweight and obese). **RESULTS:** More than 50% of adult participants were either overweight or obese in 2000/2001. When classified by BMI categories, obese individuals were more likely to be older, males, have more comorbidities, a lower quality of life and higher one-year medical costs. A Generalized Linear Model (GLM) indicated that age, gender, obese, being inactive and smoker increased significantly the total costs. Compared to normal weight adults, being underweight or obese were also positive predictors of costs. Health-related quality of life, income or being overweight had no impact on costs. **CONCLUSIONS:** These results suggest that the burden of obesity in Ontario is considerable.

PSY10

PREVALENCE OF METABOLIC SYNDROME AND DIFFERENCES IN HEALTH HABITS AMONG SUFFERERS AMONG U.S. ETHNIC GROUPS

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OBJECTIVES: To quantify prevalence of metabolic syndrome in U.S. ethnic groups and determine ethnic differences in health habits among sufferers. **METHODS:** Data were obtained from the 2008 U.S. National Health and Wellness Survey (NHWS), a national, patient-reported, Internet-based study of health care attitudes, behaviors, health status, and outcomes of adults aged 18+. Metabolic syndrome was defined as experiencing at least three of the following: type 2 diabetes, high cholesterol, hypertension, BMI ≥ 30. Smoking, regular exercise (16+ times/month), visiting a physician in the past six months, and insurance status were assessed. Frequency weights based on age, race and gender were used to calculate prevalence estimates. Logistic regression was used to determined effects of ethnicity on metabolic syndrome and health habits among sufferers while adjusting for other demographics. Analyses were limited to self-identified white (reference group), black, Hispanic and Asian respondents. **RESULTS:** Of the 61,016 respondents, 9.0% (projected 16.7M; 7.8%) experienced metabolic syndrome. Prevalence varied across ethnic groups: White = 12.8 M, 8.4%; Black = 19.5 M, 7.9%; Hispanic = 1.6 M, 5.8%; Asian = 0.3 M, 3.2%). Adjusting for other demographics, blacks were more likely (OR = 1.35, $p < 0.01$), Asians less likely (OR = 0.58, $p < 0.01$), and Hispanics equally as likely to have metabolic syndrome as whites. There were significant ($p < 0.05$) ethnic differences in selected health habits among sufferers after adjusting for other demographics. Specifically, Hispanics were 0.69 times as likely to be current smokers and 0.69 times as likely to visit a primary care physician as whites, and blacks were 0.64 times as likely to have health insurance as whites. **CONCLUSIONS:** Complex conditions such as metabolic syndrome present new challenges in ethnic health and health care research due to variations in the prevalence and risk factors by ethnic groups. Among metabolic syndrome sufferers, ethnic disparities in health habits, physician visits, and insurance status may lead to differential outcomes by ethnic group.

PSY11

ESTIMATION OF CAUSAL EFFECTS OF PHYSICAL ACTIVITY ON OBESITY BY A RECURSIVE BIVARIATE PROBIT MODEL

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OBJECTIVES: The study objective was to quantify the causal effect of physical activity (PA) on obesity controlling for unobservable factors causing bias. **METHODS:** Data from the MEPS's Household Component (2006), a nationally representative survey of the U.S. civilian non-institutionalized population, were used. Analysis accounted for the survey's clusters, strata and sampling weights. Treatment variable was a binary indicator if an individual spent half hour or more in moderate to vigorous physical

activity at least three times a week. Obesity (OB) was defined by a binary indicator if body mass index was greater than 30. The structural parameter, average treatment effect (ATE) was defined as the impact of PA on obesity, if individuals are randomly assigned to PA. The second parameter average treatment in the treated (ATET) measured the impact of PA on obesity amongst those who became physically active, rather than for the population as a whole. To control for the unobservable factors affecting PA, we specified a recursive bivariate probit model. To avoid identification based on functional form, instruments added were presence of any limitations, and injury. Covariates included age, gender, race, ethnicity, geographical and metropolitan area location, smoking status, comorbidities and perceived physical and mental health. **RESULTS:** Based on naïve probit model, the probability of obesity, evaluated at the means of the data, was 0.099 lower amongst those who were physically active ($p < 0.001$). Effect of selection bias was positive and significant (rho = 0.55 $p < 0.001$). Based on the recursive probit model, ATE was a 27.7% decrease (95% CI –0.279 to –0.275) while ATET was a 38.8% decrease (95% CI –0.391 to –0.385) in probability of obesity amongst those who were physically active. **CONCLUSIONS:** Unobservable heterogeneity may be masking the true effect of physical activity on obesity. Accounting for this bias confirms a significant protective effect of physical activity against the likelihood of obesity.

PSY12

TREATMENT OF TRANSFUSIONAL IRON OVERLOAD IN PATIENTS WITH MYELODYSPLASTIC SYNDROME OR SEVERE ANEMIA: DATA FROM MULTI-CENTER CLINICAL PRACTICES

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OBJECTIVES: Patients with myelodysplastic syndrome (MDS) or severe anemia requiring repeated transfusions of red blood cells (RBCs) risk developing transfusional iron overload (TIO), which can cause organ damage and reduce survival. Iron chelation therapy (ICT) has been shown to improve survival and quality of life in patients with TIO; however, ICT utilization in clinical practices is not well understood. **METHODS:** The medical records of patients diagnosed with MDS or severe anemia ≥6 months before data extraction, aged ≥ 21 years at their diagnosis, received ≥1 RBC transfusion were reviewed. ICT-eligibility was defined as ≥20 units of RBCs transfused or ≥2 serum ferritin (SF) tests ≥1000 mcg/L. Study endpoint was ICT-treatment rate among ICT-eligible patients with lower-risk MDS [IPSS (low or intermediate-1); WHO (RA, RARS, RCMD, RCMD-RS or 5q); FAB (RA or RARS)]. Characteristics and survival of treated and untreated groups were described. **RESULTS:** Medical records data for 283 patients were extracted. Among 78 ICT-eligible patients with lower-risk MDS, only 32 (41%) received ICT. At ICT-initiation, treated patients received on average 13.3 transfusions (27.6 units) and mean first SF near-ICT-initiation was twice the recommended level at 1949 mcg/L. Median overall survival for all ICT-eligible patients was significantly longer for those ICT-treated than untreated (8.7 versus 4.7 years, log-rank $p = 0.02$; multivariate hazards ratio = 0.372, $p = 0.03$). **CONCLUSIONS:** This observational study finds only 41% of ICT-eligible patients with lower-risk MDS received ICT in clinical practice, and their treatment was initiated later than recommended. Among all ICT-eligible patients, those who received ICT had a significantly better overall survival than untreated patients.

PSY13

FREQUENCY AND BOTHERSOMENESS OF SIDE EFFECTS IN PAIN PATIENTS TAKING OXYCODONE IMMEDIATE RELEASE: IMPACT ON PRESCRIPTION AND OVER-THE-COUNTER MEDICATION USE

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OBJECTIVES: Oxycodone immediate release, alone or in combination (oxycodone), is widely used to treat pain. However, oxycodone is often associated with bothersome side effects, which may lead to increased medical resource use, including prescription and over-the-counter (OTC) medications. The objective of this first analysis was to assess the frequency and bothersomeness of side effects and other medication use among patients taking oxycodone. **METHODS:** An online survey was completed by a nationwide convenience sample of patients currently taking oxycodone for non-malignant pain. Detailed data on patient experience with oxycodone were collected. A minimum sample size of 600 was determined to ensure reasonably accurate estimates around the frequency of side effects and medical resource utilization. **RESULTS:** Among the 601 respondents [mean age of 45 years (range 18–86), 85.0% Caucasian, 69.1% female], almost half, 45.6%, were taking oxycodone for back/neck pain, 16.8% for osteoarthritis/rheumatoid arthritis, 14.3% for pain due to injury/trauma, 10.5% for recent surgery, 7.2% for fibromyalgia, and 5.7% for neuropathic pain. The mean daily dose was 16.5 mg (range 2.5–200). Overall, 83.5% were bothered by side effects with 29.9% being moderately/extremely bothered. Over half, 53.1%, were bothered by constipation, almost one-third, 31.3%, by nausea, 27.6% by pruritus, and 14.8% by vomiting, among others. A significantly higher proportion of respondents bothered by side effects reported use of prescription (13.1% vs. 0%; $p < 0.001$) or OTC (20.5% vs. 9.1%; $p = 0.007$) medications to manage those side effects, compared to respondents not bothered by side effects. **CONCLUSIONS:** The majority of survey respondents experienced side effects of oxycodone, some of which led to the use of prescription and OTC medications. These results point to the potential benefits, both humanistic and economic, of better-tolerated pain medications. Further analyses of this data will assess the health status, pain intensity, and other resource utilization among oxycodone users.

PSY14

TOLERABILITY OF INTRAVENOUSLY ADMINISTERED IMMUNE GLOBULIN IN THE HOME SETTING

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OBJECTIVES: Patients with primary immune deficiencies and many neurological disorders are frequently treated with immune globulin, administered intravenously or subcutaneously. The aim of this study was to evaluate tolerability of intravenously administered immune globulin products in patients in the home setting. **METHODS:** A retrospective, longitudinal cohort analysis of patients (18 years and older) provided intravenous immunoglobulin (IVIG) using data from the Accredo Therapeutics electronic medical record was conducted. Inclusion criterion was infusion of at least one dose of IVIG during the study period. Patients were followed from July 1, 2007 to June 28, 2008. Three components to estimate tolerability were evaluated. The first was aggregate adverse drug event rate. The second was infusion completion rate (ICR), calculated by dividing the number of successful infusions by the number of attempted infusions. The third measure was a managed therapy completion rate (MTCR-A) for patients that had an identified ADE and were still managed to completion of therapy. **RESULTS:** The sample size for review was 33,065 doses of IVIG dispensed during the study period. The results based upon the three measures of tolerability were: 1) an ADE rate of 2.35% (95% CI: 1.79%–2.93%) based on 778 reported adverse drug events; 2) an infusion completion rate (ICR) of 99.74% (95% CI: 99.65%–99.82%); and 3) a managed through completion of therapy (MTCR-A) of 88.6% (95% CI: 80.8%–92.35%). Gender, age, diagnoses and BMI were also evaluated for their effect upon tolerability of infusion. **CONCLUSIONS:** Intravenous administration of immune globulin is an important alternative infusion option for patients. Patients can be well managed in the home on intravenously administered immunoglobulin. These findings contribute to previous research related to safety of administration of immunoglobulin in the home.

SYSTEMIC DISORDERS/CONDITIONS – Cost Studies

PSY15

THE IMPACT OF ADHERENCE ON THE COSTS AND BENEFITS OF INTENSIVE LIFESTYLE MANAGEMENT (ILM) IN OVERWEIGHT AND OBESE PATIENTS AT HIGH RISK FOR TYPE-2 DIABETES MELLITUS (T2DM)

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OBJECTIVES: The Diabetes Prevention Program (DPP) demonstrated that ILM improves lipid values, reduces blood pressure and reduces the risk of developing T2DM. Controversy over magnitude of whether these benefits can be achieved cost-effectively has diverted attention from questions about the generalizability of the results. The high rate of treatment adherence in the DPP may not be reproducible in actual practice. The objective of this study was to assess the impact of treatment adherence to ILM on estimates of health benefits and costs for a cohort of overweight and obese patients at high risk of developing T2DM. **METHODS:** The IHE/JNJ weight management model, a Markov-based, micro-simulation model that includes relevant co-morbidities and risk factors, was used to simulate the costs and health outcomes of ILM over 25 years for 500 cohorts of 1,000 hypothetical overweight and obese pre-T2DM patients. Efficacy and baseline population characteristics were taken primarily from the DPP. Costs for ILM and care associated micro- and macro-vascular complications and other co-morbidities as well as quality-of life data was obtained from existing literature. Four scenarios were assessed: adherence as observed in the DPP and reductions in the DPP adherence rate by 25%, 50%, and 75%. **RESULTS:** In all, ILM resulted in 19.96 undiscounted life years (LYs), 18.03 undiscounted quality-adjusted life years (QALYs), at a cost of $78,965, assuming DPP-like adherence. Forty percent of the cohort ultimately developed T2DM. Reducing adherence by 25%, 50%, and 75% reduced LYs by 0.17, 0.29, and 0.40, QALYs by 0.36, 0.68, and 1.03, and increased costs by $2154, $4190, $6813, respectively. The rate of T2DM transition increased by 5, 10, and 15 percentage points, respectively. **CONCLUSIONS:** Patient adherence is an important driver of the benefits and costs of ILM and should be considered explicitly in cost-effectiveness estimates.

PSY16

A CANADIAN BASED PHARMACOECONOMIC ANALYSIS OF SELECTED ANTICONVULSANTS, SNRIS AND TCAS IN TREATING NEUROPATHIC PAIN

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OBJECTIVES: Neuropathic pain starts as or is caused by a primary lesion or dysfunction in the nervous system. It impacts use of health care resources and may incur employment disruptions. The primary goal in managing neuropathic pain is to make it more tolerable. Three classes of atypical medications, anticonvulsants (ACs), sero-